UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
THIS DOCUMENT RELATES TO 01-CV-12257-PBS and 01-CV-339	Judge Patti B. Saris

TRIAL OF CLASS 2 AND 3 CLAIMS

THE JOHNSON & JOHNSON
DEFENDANTS' POST-TRIAL MEMORANDUM

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Johnson & Johnson, Centocor, Inc., and Ortho Biotech Products, L.P. ("the J&J Defendants") respectfully submit this post-trial memorandum in support of their demand for entry of judgment of no liability as to Class 2 and Class 3.

I. JUDGMENT SHOULD BE ENTERED IN FAVOR OF THE J&J DEFENDANTS WITH RESPECT TO PROCRIT AND REMICADE FOR ALL CLAIMS BY PAYORS IN CLASS 2 AND CLASS 3.

The facts bearing on the J&J Defendants are either admitted or essentially uncontested. The pricing on Procrit and Remicade was transparent. The "spreads" on both drugs were within Dr. Hartman's estimate of what payors allegedly expected. The J&J Defendants' pricing and marketing practices were not deceptive or unfair.

Judgment in favor of the J&J Defendants is fully warranted with respect to Class 2 and Class 3.

A. Judgment Should Be Entered In Favor of the J&J Defendants Because the Spreads on Procrit and Remicade Were Less than 30%.

Plaintiffs contend that payors knew that manufacturers sometimes gave providers discounts below the wholesale acquisition price (WAC), but did not expect that these discounts would produce "spreads" between AWP and average selling price (ASP) greater than 30%. Accordingly, plaintiffs assert liability as to spreads greater than 30%, but do not assert liability for spreads of 30% or less.

This theory is wrong for many reasons, not the least of which is that manufacturers could not have known their prices were illegal because Dr. Hartman's 30% "speed limit" was not posted in any statute or regulation. Even so, in the case of Procrit and Remicade, application of a 30% speed limit leads to a finding of no liability, because the spreads on these drugs were 30% or less throughout the class period.

Plaintiffs admit that all of Procrit's spreads were less than 30%. (Johnson & Johnson Defendants' Proposed Findings ("J&J PF"), ¶ 19). Plaintiffs concede, therefore, that there is no liability for Procrit in Class 3. (Berman, Nov. 6 Tr. 28; Berman, Nov. 7 Tr. 121).

Plaintiffs also admit that Remicade's spreads were 30% or less in 1998, 2000, 2002, and 2003. (J&J PF ¶ 45). Dr. Hartman calculated Remicade spreads of 32.1% and 31.9% in 1999 and 2001, respectively, but his calculations in those years were biased by the fact that he compared Remicade's ASPs to the AWPs in effect on June 30th, rather than to the average AWPs in effect for the entire year. This artificially inflated the two Remicade spreads at issue because Remicade's AWP in those years was higher on June 30th than it was during most of the first half of the year. When Mr. Dukes compared Dr. Hartman's ASPs to the average or weighted average AWPs, the spreads on Remicade were 30% or less throughout the class period. (Id.).

In their rebuttal case, plaintiffs did not challenge the accuracy of Mr. Dukes' calculations. Rather, Dr. Hartman defended his use of June 30th AWPs, by arguing, in general, that "to the extent that a midpoint value might overstate damages for one period, it will understate damages for another, resulting in a fair estimate of aggregate damages." (Hartman Rebuttal, ¶ 25).

Dr. Hartman's "rough justice" argument does not apply to Remicade. If average or weighted average AWPs are used instead of the AWPs in effect on June 30th, Remicade's spread never exceeds 30%. (J&J PF ¶ 45). Dr. Hartman's damages estimates for Remicade are not "understated" at any time during the class period. Plaintiffs do not claim otherwise.

Plaintiffs' 30% liability theory begins and ends with the size of the spread. Under this theory, where the spread is 30% or less, there is no deception or unfairness, and Ch. 93A is

not violated. (Berman, Nov. 6 Tr. 28; Berman, Nov. 7 Tr. 121). Because the Procrit and Remicade spreads never exceeded 30%, the J&J Defendants are entitled to entry of judgment.

B. Plaintiffs' "Per Se" Or "Zero Spread" Liability Theory For Class 2 Should Be Rejected.

Plaintiffs propose a more radical theory for Class 2. Even though Dr. Hartman admits that payor expectations were the same in Class 2 and Class 3, and even though he originally applied his 30% expectation theory to both classes, plaintiffs now claim spreads are unlawful per se, because, in the Medicare context, AWP is supposed to mean ASP. Under this theory, all spreads are illegal.

Plaintiffs' per se theory should be rejected for the reasons stated in the Track 1 defendants' joint brief. (See Memorandum of Law in Support of Track 1 Defendants' Post-Trial Motion for Judgment). As the Court noted during the trial, liability cannot be based on the mere fact of a spread. Plaintiffs must still prove that each defendant's pricing and marketing practices were unfair or deceptive. (Nov. 8 Tr. 168) ("even if it's, I think, a statutory violation, that's different from unfair and deceptive acts….").

The fallacy of plaintiffs' per se theory is evident from the fact that it produces an absurd result. Were this Court to rule that any spread is illegal, regardless of a company's good faith, and regardless of whether the spread is 20% or 2000%, no drug would escape liability. All prescription drugs sold in the United States have spreads of 20% to 25% or more, and, as plaintiffs concede, everyone knew it. (See Track 1 Defendants' Proposed Common Findings of Fact ("CFF") ¶¶ 1, 76, 100-102).

In considering whether a defendant's conduct violates Ch. 93A, courts should consider whether the defendant's conduct comports with industry norms and standards. Commercial Union Ins. Co v. Seven Provinces Ins. Co., Ltd., 217 F.3d 33, 43-44 (1st Cir. 2000)

(affirming judgment that reinsurer had engaged in unfair conduct under 93A based on, inter alia, expert testimony regarding "the traditional mores of the industry")[1] Yet a ruling that spreads are unlawful per se would conflict with plaintiffs' concession that the AWP reimbursement system "works" for "99 percent" of the drugs sold in the United States, including hundreds of drugs administered by physicians. (Rosenthal, Nov. 27 Tr. 69-70, 83). Despite years of scrutiny, AWP-based reimbursement continues to find favor with most private payors, including BCBS/MA and other Massachusetts insurers. (CFF ¶ 62, Rosenthal, Dec. 18 Tr. 21; Gaier, Nov. 29 Tr. 24-26; Devaux, Nov. 7 Tr. 136, 149-50, 153-54, 164-65; Mulrey, Nov. 8 Tr. 24-29). The record is replete with testimony from third-party payors who understood that AWP did not equal acquisition cost, knew about (and benefited from) discounts and rebates below WAC, and never thought AWP meant ASP or acquisition cost. (CFF ¶¶ 31-46, 62-65).

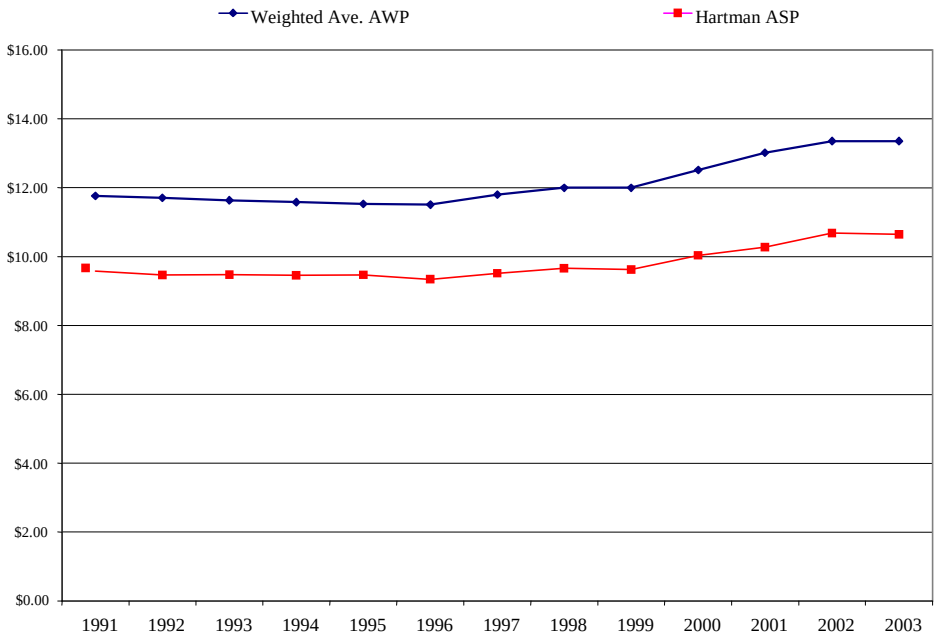
There is no evidence that payors in Class 2, which frequently are the same payors who comprise Class 3, expected there to be "zero" difference between ASP and AWP. Dr. Rosenthal, for example, acknowledged that for the thousands of drugs sold in the United States between 1991 and 2003, "there has always been some difference between AWP and transaction prices." (Rosenthal, Nov. 27 Tr. 83). In her opinion, a drug's AWP and its actual selling price should "track [each other] but certainly not be equal." (Id. at 71) (emphasis added). She

[1] See also Salisbury v. Monumental Life Ins. Co., 1 F.Supp.2d 97, 103 (D. Mass. 1998) (Saris, J.) (on summary judgment, denying 93A claim for unfair and deceptive settlement practices based, inter alia, on "the general nature of the policy as group life insurance as understood under industry (albeit not statutory) standards."); James L. Miniter Ins. Agency, Inc. v. Ohio Indem. Co., 112 F.3d 1240, 1251 (1st Cir. 1997) (finding no 93A unfairness when insurer "adhered to the industry custom"); Govoni & Sons Constr. Co., Inc. v. Mechanics Bank, 742 N.E.2d 1094, 1107 (Mass. App. Ct. 2001) (finding no unfairness when procedures were "widely utilized by similar banks in the area"); USM Corp. v. Arthur D. Little Sys., Inc., 546 N.E.2d 888, 898 (Mass. App. 1990) (affirming judgment that no unfair or deceptive acts occurred when plaintiff, "a sophisticated business entity . . . was not misled," and when the seller's "financial reporting practices were in conformity with accepted methods within the business community").

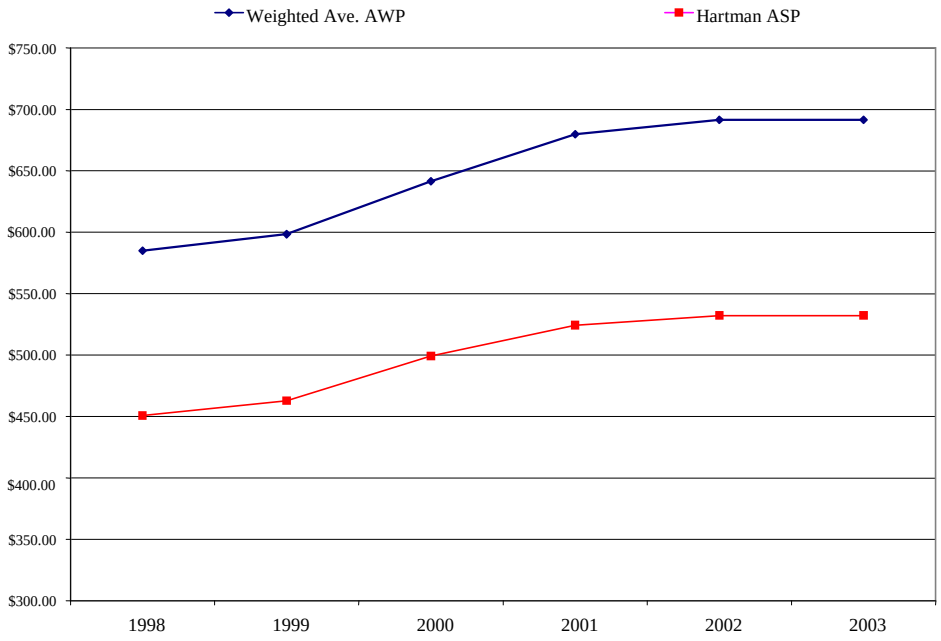
described the "but for" world as one where the reported AWPs "were consistent in tracking ASP within some reasonable amount." (Id. at 85-86) (emphasis added). She agreed that 20% to 25% markups between WAC and AWP were "universally known" to third party payors "throughout the class period," and that this difference "made up the bulk of the markup of the 30 percent speed limit." (Id. at 71-72; see also Rosenthal, Nov. 15 Tr. 94 (standard markup was understood "during the class period")). She said her concern was not with spreads per se, but rather with spreads that were "too big." (Rosenthal Nov. 27 Tr. 71; see also Rosenthal, Nov. 15 Tr. 93-94 (spreads should not be "substantially more" than the standard markup)).

By the standards espoused by plaintiffs' experts, the spreads on Procrit and Remicade were not deceptive or unfair. The J&J Defendants priced their drugs in good faith in a manner consistent with industry norms that pre-date the class period by decades. (Bell, Nov. 28 Tr. 103-04 (standard markup dates from the 1970's); Rosenthal, Nov. 15 Tr. 86-87 (standard markup established by the pricing services and/or the wholesalers)). Their spreads were within Dr. Hartman's yardstick. The "bulk" of Procrit's spread – and "all" of Remicade's spread – came from the published markup between the WAC and AWP. Moreover, their ASPs precisely "tracked" their AWPs, as shown in the following charts, which are derived from the figures on DX 2873:

Procrit: ASP vs. AWP
(All NDCs)



Remicade: ASP vs. AWP



These undisputed facts led Dr. Rosenthal to admit that Procrit is one of the hundreds of physician-administered drugs and thousands of self-administered drugs for which

the AWP-based reimbursement system "works." (Rosenthal, Nov. 27 Tr. 69-70). Of course, the system worked for Remicade as well, because its pricing was transparent. Plaintiffs admit that (1) the 30% WAC-to-AWP spread on Remicade was "published" by the price reporters, (2) the published WAC-to-AWP spreads were "reflective of" the spreads between ASP and AWP, and (3) the relationship between Remicade's ASP and AWP, because it remained constant, was "fairly predictable." (DX 2782 (Response to Request to Admit No. 2); Hartman, Nov. 21 Tr. 128-29; Rosenthal, Nov. 27 Tr. 73-74, 82).

During the trial the Court asked plaintiffs to provide alternative damages calculations for Class 2 in case the Court decides to adopt a 30% liability threshold. (Nov. 8 Tr. 167-69). Those calculations confirm that a 30% liability threshold yields zero liability and damages for Procrit and Remicade. (PX 4008; Hartman, Dec. 11 Tr. 95).

C. The J&J Defendants' Pricing and Marketing Were Not Deceptive or Unfair.

The absurdity of finding per se liability based on the existence of any spread is underscored by the fact that Procrit and Remicade do not fit within what plaintiffs call the "AWP scheme." That scheme involves three basic elements: (1) opaque pricing due to "secret" discounting to doctors; (2) the lack of a predictable relationship between AWP and ASP, and (3) increasing spreads to drive market share by increasing the physician's profit. (See, e.g., Rosenthal Direct ¶¶ 71-74; Hartman Direct ¶¶ 4-6, 21-25, 92).

The J&J Defendants' conduct is not remotely consistent with this alleged scheme.

1. Procrit's Pricing and Marketing Were Not Deceptive or Unfair

Procrit (epoetin alfa) is used to treat anemia. (J&J PF ¶ 1). Procrit was launched in January 1991. (Id. at ¶ 5). Its published WAC-to-AWP spread, which was established before HCFA first proposed using AWP as a reimbursement benchmark, was 20%. (Id. at ¶ 6).

Procrit's WAC prices, and its corresponding AWPs, were equal to, or less than, the WAC prices and AWPs established 18 months earlier for Epogen, a brand of epoetin alfa sold by Amgen, Inc. (Id.). Except for the difference in brand names, Procrit and Epogen are exactly the same. (Id. at ¶ 2).

Procrit is sold under a license agreement with Amgen that gives Ortho Biotech the exclusive right to promote Procrit for use in treating anemia in non-dialysis patients. (Id. at ¶ 3). In order to encourage providers who were treating non-dialysis patients with Epogen to switch to Procrit, Ortho Biotech offered non-dialysis providers modest price incentives below the published WAC price. (Id. at ¶ 7). Ortho Biotech did not conceal these incentives. (Id. at ¶ 8). To the contrary, the incentives were advertised by Ortho Biotech and its distributors. Defendants' Exhibit 2758 is an example of a Procrit promotional flyer. It conveys Ortho Biotech's 8% physician rebate offer on Procrit purchased for non-dialysis between January 4, 1993 and July 2, 1993.

As noted above, the minimal discounts on Procrit did not result in large spreads. Dr. Hartman made a total of 114 spread calculations on Procrit and found that none of them exceeded 30%. (Hartman Direct, Attachment G.3.c). Ninety one of these 114 spreads were between 20.1% and 25%. (Id.). Because the discounts were so small, Procrit's ASP and AWP tracked each other throughout the class period. (See Procrit ASP vs. AWP Chart, supra at 6). Ortho Biotech did not increase Procrit's AWP while lowing its ASP. (Id.).

Any payor who understood the rudiments of the AWP system, i.e., that the WAC-to-AWP spread typically is 20% to 25%, and that providers sometimes receive discounts below WAC, could not possibly have been deceived by Procrit's pricing. Drs. Hartman, Bell and

Rosenthal all agreed that these basic aspects of the AWP system were well-understood. (Hartman Direct ¶ 6; Bell, Nov. 28 Tr. 132-34; Rosenthal, Nov. 27 Tr. 71-72).

Moreover, throughout the class period, Ortho Biotech had a steadfast policy that its sales representatives should not sell Procrit by marketing the difference between AWP and acquisition price. (J&J PF ¶ 19). The cost calculators it distributed in 2002 were consistent with this policy. The spreadsheet given to doctors contained information about the cost of acquiring Procrit, but did not reference reimbursement rates or permit physicians to calculate spreads. (Id.). The company distributed a different spreadsheet to third-party payors that showed that the cost of reimbursing Procrit based on AWP was lower than for a competing product. (Id.). Neither spreadsheet could be used to "market the spread." (Id.).

Plaintiffs questioned Ortho Biotech's rigor in enforcing this policy because, in 1996, a former District Manager in Minnesota wrote a memo to the ten sales representatives in his District stating that they could discuss profit with physician offices if pressed, but that the numbers should written on "scratch paper." (PX 268). At his deposition the former manager testified that, notwithstanding his memo, he never discussed profits with any of the physicians he called upon and he did not observe any sales representatives in his District doing so. (J&J PF ¶ 20). A more senior Ortho Biotech executive described the memo as an unauthorized departure from Ortho Biotech policy. (Id.).[2]

There is also no question that the government was generally aware of Procrit's actual market prices. In fact, Procrit pricing was the subject of three separate reports published

[2] Although required to do so in order to sustain a claim under Ch. 93, § 11, plaintiffs offered no evidence concerning Ortho Biotech's marketing practices in Massachusetts. Kuwaiti Danish Computer Co. v. Digital Equipment Corp., 438 Mass. 459, 473, 781 N.E.2d 787, 799 (2003) (plaintiff must prove that conduct at issue occurred "primarily and substantially" in Massachusetts).

by different agencies of the federal government. The first report was prepared for Congress by the Office of Technology Assessment. (DX 1046; J&J PF ¶ 11). The OTA report was published in May 1990, before Procrit was launched. It highlighted several different reimbursement options for epoetin alfa, including the use AWP. The OTA advised Congress that "[a]verage wholesale prices, however, are usually list prices instead of the transaction prices that providers actually pay for pharmaceuticals." (DX 1046 at 21). Although Procrit was not yet available in the market, the OTA predicted that Ortho Biotech would likely need to offer "price concessions and other benefits" in order to overcome Epogen's "brand loyalty" from being the "first brand on the market." (Id. at 71).

A second report addressing Procrit's pricing was issued in 1997 by the Office of Inspector General. (DX 1075; J&J PF ¶ 12). The OIG looked at market pricing with respect to 22 Part B drugs, including Procrit. The OIG found that, for roughly half of the drugs studied, a switch from AWP-based reimbursement to reimbursement at "acquisition cost" would yield savings in excess of 40%. (DX 1075 at 7-8 and C-2, C-3). Not surprisingly, because Procrit's discounts were comparatively modest, the percentage savings on Procrit from switching to acquisition cost instead of AWP would have been much less than 40%. In fact, the potential savings on Procrit were the lowest or among the lowest of any of the 22 drugs studied. (Id. at C-2, C-3).

HCFA was afforded an opportunity to respond to the OIG's findings. Its response, which was signed by Nancy-Ann Min DeParle, HCFA's Deputy Administrator, noted that while HCFA agreed with the OIG that Medicare reimbursement based on AWP should be lowered, HCFA was constrained by Congress from reimbursing Part B drugs at acquisition cost (id. at D-3):

> We agree with OIG's findings and recommendations. We included a provision in the President's 1998 budget bill that would have eliminated the markup for drugs billed to Medicare by requiring physicians to bill the program the actual acquisition cost for drugs. Unfortunately, this provision was not enacted, but we will pursue this policy in other appropriate ways.

Procrit's market pricing was also studied by the General Accounting Office in 2001. (DX 1098; J&J PF ¶¶ 13-14). The GAO study looked at 31 Part B drugs, including Procrit. (DX 1098 at 11-14, Tables 4 and 5). Based on its review of wholesale price lists, the GAO calculated an "Average widely available discount from AWP." In addition, the GAO used physician invoices to calculate a "Low volume [physician] billers' average discount from AWP." (Id.)

The GAO report confirmed the OIG's earlier finding that Ortho Biotech's discounts resulted in comparatively modest spreads. The "Average widely available discount from AWP" for Procrit was 15.2% [a "spread" of 17.9%]. (Id. at Table 4). The comparable range of discounts from AWP for all drugs was 12.8% to 85.6% ["spreads" of 14.8% to 606%]. The "Low volume [physician] billers' average discount from AWP" for Procrit was 22.1% [a "spread" of 28.3%]. (Id. at Table 5). The comparable range of discounts for all drugs was 15.7% to 90.4% ["spreads" of 18.8% to 943.5%].

The government's understanding of Procrit's market pricing was augmented during conversations in the mid-1990's between HCFA officials and Cathleen Dooley, Johnson & Johnson's Executive Director of Federal Affairs. Ms. Dooley discussed Procrit's pricing with

several HCFA and CMS officials, including Nancy-Ann Min DeParle and others. (J&J PF ¶ 15).[3]

Plaintiffs introduced memos written by Ms. Dooley in the mid-1990's in which she commented that, because AWP exceeds acquisition cost, physicians earned a "windfall" on Part B drugs, including Procrit, and the government was therefore considering adopting alternatives to AWP-based reimbursement. She also noted that HCFA had not surveyed drug prices in order to establish Estimated Acquisition Costs, and, consequently, did not know what physicians were actually paying for Part B drugs. (J&J PF ¶ 22).

As Ms. Dooley explained, these memos merely stated the obvious: the reimbursement amount for Part B drugs was greater than acquisition cost, this premium was partly offset by chronic shortfalls in service reimbursement, and HCFA did not know precisely what physicians paid for Part B drugs because it had not conducted surveys. (Id. at ¶ 23). But as the OIG and GAO reports demonstrate, the government certainly knew the range of Procrit's pricing. As Ms. Dooley testified, "I did not mean to suggest, nor did I believe, that the government was not aware that physicians were earning positive margins on Part B drugs, including Procrit, or that the government was unaware of the fact that Procrit was sold for less than AWP." (Id.).

In 2002, Amgen introduced Aranesp, a competing drug used to treat anemia in dialysis and non-dialysis patients. The WAC-to-AWP spread on Aranesp was 25%. From a

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[3] She explained to them that Ortho Biotech offered minimal discounts from the published WAC price and, consequently, Procrit did not have a large spread. (J&J PF ¶ 15). Ms. Dooley's discussions with HCFA officials were designed to assure them that AWP-based reimbursement worked for Procrit because its spread was not excessive. (Id.). In Ms. Dooley's many discussions with federal officials, no one suggested to her that Procrit's AWP, which remained fixed at 20% above the WAC price, and which did not reflect Procrit's modest discounts and rebates, was unlawful or otherwise improper. (Id. at 16).

reimbursement perspective, this put Procrit at a competitive disadvantage. (Id. at ¶ 24). In order to redress this imbalance, Ortho Biotech lobbied CMS and regional Medicare Carriers to implement a "Least Costly Alternative" reimbursement policy. Under this policy, Procrit and Aranesp would have been reimbursed based on the lower of their AWPs, resulting in savings to CMS and to Medicare beneficiaries. (Id. at ¶ 25). CMS declined to implement a least-cost reimbursement policy as did all but one of the regional Medicare Carriers. (Id. at ¶¶ 26-27). The Carrier in Utah did adopt this cost-saving policy but Utah's policy was rescinded by CMS. (Id.).

Under its patient assistance programs, Ortho Biotech has given individuals of limited means about $200 million in free Procrit (valued at the WAC price). (Id. at ¶ 28). In addition it has made donations to not-for-profit foundations that help indigent Medicare beneficiaries meet their co-pay obligations. (Id.).

The J&J Defendants supported AWP reform in the months leading up to the enactment of the Medicare Modernization Act. (Id. at ¶ 29). In particular, Johnson & Johnson supported the move to "an ASP-based methodology" that would reimburse physicians at a set margin above ASP, as long as the reimbursement amount was adequate. (Id.).

In sum, there is no basis for finding per se liability as to Procrit in Class 2.

2. Remicade's Pricing and Marketing Were Not Deceptive or Unfair.

Remicade was introduced in 1998. It is used to treat Crohn's Disease and rheumatoid arthritis. (J&J PF ¶ 33).

As noted above, Remicade's pricing was transparent throughout the class period, because Centocor did not offer discounts or rebates to physicians. (Id. at ¶ 43). Because there were no discounts, Remicade's published WAC-to-AWP spread was the same as its ASP-to-

AWP spread. (Id. at ¶ 45). Centocor disclosed its WAC and AWP to HCFA when it applied for a J-Code. (Id. at ¶ 46). The spread on Remicade never exceeded 30%. (Id. at ¶ 44).

Centocor told physicians the amount they would receive in reimbursement from public and private payors. (DX 2835; PX 252; PX 254; PX 285; PX 289). Plaintiffs do not claim that the reimbursement information Centocor provided was false or misleading, or that Centocor attempted to conceal the fact that it was providing this type of information. To the contrary, Centocor's "Office-Based Infusion Guide," which contained a "Financial Impact Worksheet," was publicly available as it was posted on Centocor's web site. (Hoffman, Nov. 14 Tr. 68).[4]

Centocor's practice of discussing reimbursement with physicians was not deceptive or unfair. Plaintiffs' experts criticize instances where two or more manufacturers "compete" for the physician's business by "inflating the spread," potentially inducing the physician to choose the more expensive and possibly less effective therapy at the payors' expense. In Dr. Hartman's opinion, spread competition occurs when the AWP goes up and the ASP goes down. (Hartman, Dec. 18 Tr. 104).

Centocor did not engage in "spread competition." As Dr. Rosenthal admits Remicade's AWP and ASP moved in tandem. Neither increased without a commensurate increase in the other. (Rosenthal, Nov. 27 Tr. 71, 81-82; see also Remicade ASP vs. AWP Chart supra at 6).

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[4] Accurate and truthful discussions of the difference between Remicade's acquisition price and its reimbursement amount are protected "commercial speech" under the First Amendment to the United States Constitution. See El Dia v. Puerto Rico Dep't of Consumer Affairs, 413 F. 3d 110, 113 (1st Cir. 2005) citing Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of New York, 447 U.S. 557 (1980).

Moreover, Centocor's efforts to educate physicians about the cost and reimbursement for Remicade did not result in higher reimbursement costs. The cost to payors and patients of reimbursing for infusions in physician offices is substantially lower than in hospitals. (J&J PF ¶¶ 35, 41). By encouraging physicians to consider the financial benefits of providing in-office infusions, instead of sending patients to hospital out-patient clinics, Centocor improved the quality of medical care and reduced health care costs. (Id.; PX 252 at MDL-CEN00003481 (listing five benefits of providing Remicade infusions in the physician's office, including "providing quality health care in the most cost-appropriate setting")).

Payors cooperated with Centocor's efforts to change the site of care from hospitals to physician offices. Centocor worked directly with health insurers to reduce infusion costs by identifying physicians who were sending patients to hospitals rather than infusing them in their offices. (J&J PF ¶ 41). Centocor also made cost presentations to payors showing them the savings they could achieve by encouraging the use of Remicade in place of competing therapies. (PX 285).

Under its Patient Assistance Program, Centocor provides free Remicade to patients with incomes of 300% or less of the federal poverty level. (J&J PF ¶ 48). In addition, it has donated tens of millions of dollars to independent foundations that provide financial assistance to Medicare beneficiaries who are required to make co-pays for Part B medications. (Id.).

Plaintiffs criticize Centocor's decision to recommend a 30% markup over WAC rather than the more conventional 20% to 25% markup. This criticism is ironic because Centocor's decision to publish its entire spread resulted in greater pricing transparency, the very thing plaintiffs complain is otherwise lacking in drug reimbursement. Centocor arrived at the

30% figure based, in part, on an assessment of the amount payors would be willing to pay for Remicade in light of its value compared to other therapies. (Id. at ¶ 47). Centocor also took account of the reimbursement amount needed to ensure that it would be financially viable for physicians to provide infusion services in their offices. (Id.). Research conducted prior to launch showed that a 30% spread was not excessive compared to other products. (Id.).

In sum, there is no basis for finding per se liability as to Remicade in Class 2.

II. JUDGMENT SHOULD BE ENTERED AGAINST SHEET METAL WORKERS AND PIPEFITTERS BECAUSE THEY EITHER DID NOT PAY FOR PROCRIT AND REMICADE DURING THE CLASS PERIOD, OR PAID FOR THEM IN YEARS WHERE PLAINTIFFS ADMIT THERE IS NO LIABILITY.

In order to sustain a claim under Ch. 93A, plaintiffs must at least demonstrate that they paid for defendants' products during the class period. Roberts v. Enterprise Rent-A-Car Co., 840 N.E.2d 541, 543 (Mass. 2006). Plaintiffs must also prove they suffered a loss of money or property as a result of an alleged violation. Hershenow v. Enterprise Rent-A-Car Co. of Boston, Inc., 840 N.E.2d 526, 533 (Mass. 2006).

Plaintiffs admit that Sheet Metal Workers' National Health Fund ("SMW") did not pay for Procrit or Remicade during the class period. They further admit that Pipefitters Local 537 Trust Funds ("Pipefitters") did not pay for Procrit or Remicade in the years in which plaintiffs claim liability. Hence, neither SMW nor Pipefitters could have suffered a loss as a result of an alleged violation of Ch. 93A. Accordingly, judgment should be entered in favor of the J&J Defendants with respect to their claims.

A. Plaintiffs Admit that SMW Did Not Pay for Procrit or Remicade During the Class Period.

SMW represents Class 2 payors who provide Medigap supplemental insurance. In re Pharmaceutical Industry Average Wholesale Price Litigation, 233 F.R.D. 229, 231 (D.

Mass. Jan. 20, 2006). SMW's trustee, Mr. Glenn Randle, testified that he had no personal knowledge whether SMW reimbursed any subject drug. (J&J PF ¶ 51).

Seeking to remedy this deficiency in plaintiffs' proof, Dr. Hartman prepared a summary chart purporting to identify the years in which each class representative paid for subject drugs based on AWP. (Id. at ¶ 52). According to Dr. Hartman's chart, SMW never paid for Remicade, and it did not pay for Procrit until 2004. (Id.). SMW's payment in 2004 took place after the expiration of the class period. (Id.). The Court granted defendants' motion for summary judgment with respect to payments in 2004. In re Pharmaceutical Industry Average Wholesale Price Litigation, No. 01-12257, 2006 WL 3102998 (D. Mass. Nov. 2, 2006).

Accordingly, the J&J Defendants are entitled to judgment against SMW because SMW did not pay for Procrit or Remicade during the class period.[5]

B. Plaintiffs Admit that Pipefitters Did Not Pay For Procrit or Remicade In the Years In Which Plaintiffs Claim Liability.

Pipefitters represents payors in Class 3. In re Pharmaceutical Industry Average Wholesale Price Litigation, 233 F.R.D. 229, 231 (D. Mass. Jan. 20, 2006). As a member of Class 3, its claims are limited to years in which the AWP allegedly exceeds 30%.

Pipefitters' Fund Administrator, Mr. Charles Hannaford, testified that he had no personal knowledge whether Pipefitters paid for any of the subject drugs listed in his trial affidavit. (J&J PF ¶ 53) (disclaiming personal knowledge of statements in paragraph 12). Dr. Hartman's chart indicates that Pipefitters paid for Procrit in 2000 and 2003, and that it paid for

[5] In fact, SMW failed to prove that it paid for "Procrit," even in 2004. The source documents alleged to support PX 4012 indicate that SMW paid for epoetin alfa as identified by HCPCS Code "Q0136." (SMWMASS0012-13). This designation covers both Amgen's Epogen and Ortho Biotech's Procrit when they are used to treat anemia in non-dialysis patients. (Dooley, Nov. 16 Tr. 52-53; see also Faulkner, Nov. 7 Tr. 14-16 (J-Code does not identify brand)).

Remicade in 2002 and 2003. (Id. at ¶ 54). Plaintiffs do not claim liability for either Procrit or Remicade in any of the years in which Pipefitters allegedly made payments, because the spreads in those years admittedly did not exceed 30%. (Id.).

Accordingly, the J&J Defendants are entitled to judgment against Pipefitters because Pipefitters did not pay for Procrit or Remicade in years in which plaintiffs allege liability.

CONCLUSION

Partway through the trial the Court observed that not all manufacturers are the same and that each company's story is different. (Dec. 8 Tr. 76). If the trial established nothing else, it showed that "individual issues are actually quite significant." (Id.).

When the facts are viewed individually, as they must be, it is clear that the J&J Defendants did not violate Ch. 93A. The spreads on Procrit and Remicade were modest. Payors were not deceived. Judgment should be entered in favor of the J&J Defendants as to Class 2 and Class 3.

Dated: January 19, 2006

Respectfully submitted,

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Certificate of Service

I certify that a true and correct copy of the foregoing was served on all parties on January 19, 2006 via LEXIS/NEXIS.

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